## EXHIBIT 2

Page 1

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC ) Master File No.

REPAIR SYSTEM PRODUCTS ) 2:12-MD-02327 LIABILITY LITIGATION ) MDL 2327

THIS DOCUMENT RELATES TO

PLAINTIFFS:

Diane Kropf

Case No. 2:12-cv-01202

JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

Judy Williams

Case No. 2:13-cv-00657

Myra Byrd

Case No. 2:12-cv-00748

Angela Coleman

Case No. 2:12-cv-01267

Susan Thamen (Reeves)

Case No. 2:12-cv-00279

Donna Zoltowski

Case No. 2:12-cv-00811

DEPOSITION OF JOSEPH M. CARBONE, M.D.

GENERAL TVT

Wednesday, March 16, 2016 Danville, Virginia

5:18 p.m.

Reported by: Karen K. Kidwell, RMR, CRR, CLR

GOLKOW TECHNOLOGIES, INC.

877.370.3377 ph | 917.591.5672 fax

deps@golkow.com

```
Page 25
                Is it fair that Exhibit 6 represents
 1
           0.
 2
     invoices that you've billed for your litigation
 3
     consulting work in this transvaginal mesh litigation?
     These are the invoices for your expert consulting
 4
     work, correct?
 5
 6
           Α.
                Yeah.
                Okay. But for the missing Prolift invoice
 7
           Ο.
     that we're going to get and add to Exhibit 6,
 8
 9
     correct?
10
           Α.
                Yes.
11
           Ο.
                Okay. Have you totaled these up?
12
           Α.
                Nope.
13
                Okay. We'll do that on break.
           Q.
14
                How many total hours have you spent in
     your role as a litigation consultant for Ethicon?
15
16
           Α.
                That's an interesting question. How many
17
     hours have I spent reviewing all the materials or how
     many hours have I billed?
18
19
           Q.
                Both.
2.0
                I spent a lot more hours reviewing the
     materials than what I billed.
21
22
           Ο.
                Okay. How many?
23
                A lot.
           Α.
                A lot?
24
           0.
25
                A lot.
           Α.
```

Page 26 More than what you billed for? 1 Q. 2 Α. Yeah. 3 O. So if we look at the invoices, we total 4 up all the hours, including with the missing invoice that wasn't brought today, we'll know the total 5 amount of hours you've billed, correct? 6 We'll know the total amount of hours that 7 Α. 8 I've billed, yes. And then you're saying that you spent more 9 working on the case above and beyond the hours that 10 11 you've actually billed, correct? 12 Α. Oh, yes. 13 Ο. Okay. And if we double the amount of 14 hours that you billed? 15 MR. MORIARTY: Objection. 16 BY MR. JONES: 17 I just want a general idea of the total 0. 18 amount of time you spent on the case. When I reviewed these articles -- I've 19 20 been reviewing this material since I was introduced 21 to the mesh in 1998. So the body of my professional 22 career was spent reviewing these materials. And in that way, I've been reviewing these materials for 23 24 over 20 years. 25 Q. Okay.

Page 27 So I would submit that I spent a career of 1 2 preparing to answer the questions you may ask me. 3 O. Okay. You've spent close to 20 years 4 reviewing materials in support of your opinions in this litigation? 5 6 MR. MORIARTY: Objection. Form. Go ahead. 7 8 THE WITNESS: Not continuously. BY MR. JONES: 9 10 Okay. For the past 20 years off and on, Ο. 11 you've reviewed -- you have reviewed materials that 12 support your opinions in this litigation? 13 Α. I've read. I've gone to CME. I've talked 14 with other clinicians. I've presented. I've been 15 involved in -- I've operated. My knowledge, my 16 training, my experience, my review of the literature, 17 my interaction with other colleagues, all that is the 18 sum of what has gone into, and more -- I'm sure I'm not touching on everything -- is the sum of what I 19 20 drew upon, if you will, to determine my opinions. Okay. And does that include review of the 21 Ο. 22 medical literature? 23 Α. Yes. 24 O. Okay. So over the course of the past 20 years off and on, you've reviewed medical literature 25

```
Page 28
     related to the topics in your report that you've
 1
 2
     written, correct?
 3
           Α.
                Off and on, yes.
 4
           Q.
                And do you continue to keep up to date
     with the medical literature on these subjects?
 5
 6
           Α.
                I try.
                You try?
 7
           Q.
                (Nodding head up and down.)
 8
           Α.
                When's the last time you did a literature
 9
           Q.
     review?
10
                Read an article?
11
           Α.
12
           0.
                Sure.
13
                I read an article last week.
           Α.
14
                Okay. What article was that?
           0.
                There was an article -- well, last week I
15
           Α.
16
     reviewed the article, the Schimph article.
17
           Ο.
                Okay. How did you find that article?
                I reviewed it -- well, I had reviewed it
18
     in the past in my general reading, and then I
19
20
     reviewed in preparation for this litigation.
21
                Was that article sent to you by Ethicon?
           Ο.
22
           Α.
                Originally, no.
                Eventually, Ethicon sent you that article,
23
           Q.
24
     though?
25
           Α.
                Eventually it was in the materials that
```

```
Page 55
                I joined a practice. I joined an existing
 1
           Α.
 2
     practice.
 3
           Ο.
                Joined an existing practice?
 4
           Α.
                Yes.
                And at the time, was that called the
 5
     Danville Urologic Clinic, now operating as
 6
     Southside -- or South -- what's the name of the
 7
     clinic that you practice at right now?
 8
 9
                Southside Urology & Nephrology.
10
                Is that the same clinic you joined in
           Ο.
11
     2000 --
12
           Α.
                Yes.
13
                -- when you came to Danville? What is the
     Piedmont Institute for Incontinence?
14
                It's called the Piedmont Institute for
15
           Α.
16
     Continence and Urinary Control.
17
           Ο.
                Okay.
18
                It's the name I gave my specific aspect of
           Α.
19
     the practice.
20
           Q.
                Is that a separate company that you've set
21
     up?
22
           Α.
                No.
23
                When Ethicon pays you as a consultant, do
           0.
24
     they pay you or the clinic?
25
           Α.
                They pay me.
```

```
Page 56
                Personally?
 1
           Q.
 2
           Α.
                Yes.
 3
           O.
                You haven't set up an LLC or a side
 4
     company to accept payment, consultant payments?
 5
           Α.
                No.
 6
           O.
                Okay. What I want to do now -- should be
     fairly uncontroversial -- is I want to get the lay of
 7
     the land for what mesh products you've used, when you
 8
     used them, and how many times you used them.
 9
10
           Α.
                Okay.
11
           0.
                And I think it might be easier to set out
12
     a little chart here. But let's start with Ethicon
13
     products. We'll start with the TVT line.
14
                How many times have you used TVT
15
     Retropubic?
16
                May I use a pen -- I'm just trying to,
17
     again, math.
18
                MR. ROSENBLATT: This isn't a written
          deposition.
19
     BY MR. JONES:
2.0
21
                Sorry. He says you can't use a pen.
           0.
22
           Α.
                Okay. That's fine.
23
                I was trying to make it easier.
           Q.
                Be patient with me as I do my math in my
24
           Α.
25
     head.
```

```
Page 57
                He'll probably let you use a pen so long
 1
           Q.
 2
     as I don't see it, though. Right?
 3
                No, I don't need to go there. Which ones
           Α.
 4
     was it the one you were asking?
 5
           Ο.
                TVT Retropubic?
 6
           Α.
                Maybe 300.
 7
           Q.
                300. Okay.
                    I'm going to go through them all.
 8
 9
                I know. I'm with you. I've got a number
10
     here, and I'm trying to figure out, based on the
11
     year, how many apparently I did. Let me give you
12
     that number.
                   Hold on.
13
                MR. MORIARTY: Is there a question
14
          pending?
     BY MR. JONES:
15
16
           Q.
                There is.
17
                Change that to about 400.
           Α.
18
           Q.
                TVT-R?
19
           Α.
                Retropubic, yeah.
20
           Q.
                Okay.
21
                I don't know. 300 to 400.
           Α.
22
           Q.
                300 to 400?
23
                Yeah, that's fine.
           Α.
24
                And the question pending was TVT-0.
           Q.
25
                200 to 300.
           Α.
```

```
Page 58
                 Okay. TVT-Secur?
 1
           Q.
 2
                 200.
           Α.
                TVT Abbrevos?
 3
           Ο.
 4
           Α.
                What is my total right now?
                                               400.
 5
           Q.
                Okay. And Exact?
 6
                Probably about 100.
           Α.
 7
           Q.
                Okay.
 8
           Α.
                Let me look at my numbers.
 9
                Yeah, sure.
           Ο.
                 That's about right, give or take a couple
10
           Α.
11
     hundred.
12
                Give or take, rough estimates?
           Ο.
13
                Yeah.
           Α.
14
           Q.
                Years.
15
           Α.
                 Okay.
                 Years and years. So let's start with TVT
16
           Q.
17
     Retropubic, since that's the oldie but goodie.
18
           Α.
                 Started in -- hmm, 2004. Four years.
19
           Q.
                 2004 you started?
20
                No, no.
           Α.
21
                No.
           Ο.
                 I started here in 2000. So about four
22
           Α.
23
     years.
24
                 Okay. TVT-0 next.
           Q.
25
           Α.
                 Uh-huh.
                          I did that probably until -- I
```

```
Page 59
     did it a while. The Secur came out what -- in,
 1
 2
     trying to remember.
               '6 or '7?
 3
           O.
 4
           Α.
                '6 or '7. Maybe picked it up in '7.
     Probably did it until like 2007, 2008.
 5
 6
                Okay. Then Secur, sometime 2007?
           O.
                2008. And I did it until Abbrevo came
 7
           Α.
     out, which is like in 2010, I think. And I've done
 8
     it pretty well since mostly. Majority of Abbrevos
 9
10
     have been since 2010.
11
           O.
                And Exact?
12
                I use, with the Abbrevo, since -- you
           Α.
13
     know, throughout the course since the -- I did the
14
     Os, since it came out.
15
           Ο.
                When did Exact come out?
16
                MR. ROSENBLATT:
                                  2010.
17
                THE WITNESS: Yeah, that's what I thought.
                And I did -- I apologize. To clarify, I
18
          did some Os, Rs, S, you know.
19
     BY MR. JONES:
2.0
21
                There's some overlap?
           0.
22
           Α.
                There's overlap.
23
                This is roughly speaking.
           O.
24
           Α.
                Yeah.
25
           Q.
                All right. So sounds like today, your
```

```
Page 78
 1
           Α.
                No.
                Do you know the stiffness of the TVT mesh?
 2
           Ο.
 3
           Α.
                No.
 4
           Q.
                Do you know the antioxidants that Ethicon
     uses in the TVT mesh?
 5
                The antioxidants?
 6
           Α.
                Sure. Do you know whether or not Ethicon
 7
           Q.
     adds antioxidants to the TVT mesh or not?
 8
 9
                Aren't antioxidants used in all Prolene?
10
     I believe antioxidants are used in all Prolene, and I
     don't know what antioxidants are used.
11
12
                There you go. That's my question. You
           Ο.
     don't know what antioxidants are used in TVT mesh,
13
14
     correct?
15
           Α.
                Correct.
16
           Ο.
                Okay. Do you know the name of the resin,
17
     polypropylene resin, used in TVT mesh?
18
                The resin?
           Α.
                (Nodding head up and down.)
19
           Q.
2.0
           Α.
                No.
21
                Do you consider yourself a materials
           0.
22
     expert?
23
                Well, what do you mean by "materials
           Α.
24
     expert"?
25
           Q.
                Do you -- will you be -- do you consider
```

```
Page 79
    yourself an expert in the properties of the TVT mesh?
 1
 2
                I believe that I am an expert in the
 3
     clinical properties of the TVT mesh. If you ask me
 4
     do I have a Ph.D. in material science? No, I don't.
     Have I spoken with material scientists? Yes.
 5
     I, you know, interacted with them? Have I talked to
 6
     them about the Amid classification? Have I taught on
 7
     the mesh itself? Have I used -- most importantly,
 8
     have I used the mesh -- my experience with the mesh
 9
10
     clinically and how it works in vivo?
11
                I would say that I have an expert -- I
12
     have a -- a knowledge and a -- I have knowledge and
13
     training and experience that would allow me to
14
     provide expert opinion in that context.
15
           Ο.
                Does the TVT mesh degrade inside a woman?
16
                I don't believe so.
17
                Have you reviewed any test by Ethicon of
           0.
     the mesh used in TVT that concludes the mesh does
18
     degrade?
19
2.0
                Say it again?
21
                Sure. Have you reviewed any medical
           0.
22
     literature that disagrees with you that mesh does not
23
     degrade inside a patient?
                I have not reviewed any Level 1 material
24
25
     randomized controlled trials to that effect.
```

```
Page 80
                Okay. That's not -- I didn't ask about
 1
           Q.
 2
     Level 1. I'm just asking about any medical
 3
     literature.
 4
                MR. MORIARTY: Objection.
 5
                Go ahead.
                THE WITNESS: Geez. I quess I'm sure, as
 6
          I've gone around -- I mean, I've done a lot of
 7
 8
          review. I'm sure there is very low-evidence
 9
          material out there that would suggest that.
10
     BY MR. JONES:
11
           Ο.
                Okay. So it's fair to say that in your
     review, you've come across medical literature that
12
13
     concludes mesh degrades inside the patient, correct?
14
                When you say "inside the patient," are you
15
     talking about explanted materials or are you talking
16
     about materials that are still inside the patient?
17
           Ο.
                Either. We'll go with explant. How about
18
     that?
                Well, there's literature -- not good
19
           Α.
2.0
     literature -- there's literature that suggests that
21
     TVT or -- yeah, polypropylene TVT mesh might degrade.
22
     Yeah.
              Is there -- do you recall what literature
23
           Ο.
24
     is that? Do you recall any authors, titles?
25
           Α.
                No.
```

Page 89 Is today the first time you have ever 1 Ο. 2 given expert testimony as an expert in a transvaginal 3 mesh case? 4 Α. To the best of my recollection, yeah. 5 Is this case the first time you've ever acted as an expert in litigation in a case involving 6 transvaginal mesh? 7 Again, acted as an expert in transvaginal 8 Α. litigation mesh -- or transvaginal mesh litigation? 9 10 (Nodding head up and down.) 0. 11 Α. And that means both the TVT polypropylene Prolene mesh and the -- okay -- and the Prolift 12 13 polypropylene mesh. 14 Any mesh in transvaginal --To the best of my recollection, none of 15 16 the med mal -- and they were all med mal -- cases 17 that I reviewed were -- involved TVT polypropylene or 18 Prolift polypropylene mesh. Okay. Great. Perfect. Is this case the 19 first time you've acted as an expert in the design 2.0 and safety of a device? 21 22 Α. Expert in the design and safety. I mean, 23 the -- what do you mean by "expert"? I think we've 24 had this discussion before with respect to the expert in the materials. But now you're talking about

25

```
Page 90
     design and safety; is that correct? Different?
 1
 2
                (Nodding head up and down.)
           0.
 3
           Α.
                So I ask again the same question. What do
 4
     you mean by "expert in design and safety"?
                You don't have -- you don't understand my
 5
 6
     question of whether -- are you an expert in this case
     on the design of the TVT device?
 7
 8
                MR. MORIARTY: Objection.
                Go ahead.
 9
10
                              Insomuch as -- I'm not an
                THE WITNESS:
11
          engineer. Okay? But insomuch as I'm familiar
12
          with the design, I've used the design, I've been
13
          trained, I have experience with the design, I've
14
          read the literature regarding the design, I've
          used it clinically, I feel like I am an expert.
15
16
          But -- in that context, I believe I'm an expert.
17
          I'm not -- I'm saying that I'm not an engineer.
          I can't speak with any --
18
     BY MR. JONES:
19
2.0
                Okay. Here's my question.
           0.
21
                Go ahead.
           Α.
22
           Ο.
                Have you ever been asked by a medical
23
     device company prior to Ethicon in this case to be an
     expert in litigation?
24
25
           Α.
                Repeat it. Seriously. Just want to make
```

Page 91 sure I get it right. 1 2 Have you ever been asked by a medical 3 device company other than Ethicon to be an expert in 4 litigation? To the best of my recollection, I don't 5 believe any of the medical malpractice cases involved 6 medical devices. 7 8 Now I've got to ask you again. Yes or no. To the best of your recollection, has a medical 9 device company other than Ethicon ever asked you to 10 11 act as an expert in litigation? 12 Is it the same question? Α. 13 Ο. Yes or no? 14 Was my answer inadequate? Α. 15 Ο. Yes or no? 16 Α. Not that I recall. Okay. Perfect. 17 Ο. 18 Α. Okay. We went back and we did tally up the 19 Q. 20 payments from Exhibit 5. 21 Α. Okay. 22 So you have Exhibit 5 in front of you, and we added up those payments from Ethicon to you 23 between the years 2003 to 2012. And the total I'll 24 25 represent to you is \$452,398.

```
Page 105
                THE WITNESS: D-E-A-T-H?
 1
 2
                MR. JONES: Yes.
 3
                MR. MORIARTY: Objection.
 4
                THE WITNESS: You know what? In the form
          that you're asking it, I can't answer that
 5
 6
          question.
     BY MR. JONES:
 7
 8
           Q.
                Okay. Do you tell your patients when
     you -- before you implant a TVT device or Ethicon
 9
10
     mesh product, that you have consulted for Ethicon
     since 2003?
11
12
           Α.
                Now?
13
                We'll start with now.
           Q.
14
           Α.
                No.
15
           Ο.
                Have you ever?
16
           Α.
                Yes.
                When?
17
           0.
                When I was consulting for Ethicon and TVT.
18
           Α.
19
           Ο.
                Okay. So between 2003 -- between 2003 and
20
     2012, you told your patients you were an Ethicon
     consultant?
21
22
           Α.
                It was my usual practice.
                Currently, you don't tell -- currently,
23
           Ο.
24
     what do you tell your patients?
25
                I don't tell them I'm a consultant.
           Α.
```

```
Page 106
                Okay. Do you tell them that you're a
 1
           Q.
 2
     litigation consultant for Ethicon?
 3
           Α.
                No.
 4
           Ο.
                Okay. Do you agree that one of the risks
 5
     of the TVT mesh is chronic pain?
                I don't attribute it to the mesh.
 6
           Α.
 7
           Q.
                Is that a no?
 8
                I guess we'd say that's no.
           Α.
                Do you agree that one of the risks of the
 9
           Q.
     TVT mesh is chronic dyspareunia?
10
11
           Α.
                I don't attribute it to the mesh.
12
           Ο.
                Is that a no?
13
           Α.
                That's a no.
14
                Do you agree one of the risks of the TVT
           0.
15
     device is chronic pain in women?
16
           Α.
                I don't attribute it to the device.
17
                Is that a no?
           Ο.
18
           Α.
                That's a no.
19
           Q.
                Do you agree that one of the risks of the
2.0
     TVT device is chronic dyspareunia?
21
                I do not attribute it to the device.
           Α.
22
           Ο.
                Is that a no?
23
           Α.
                That's a no.
24
                Do you agree one of the risks of the TVT
           Ο.
25
     mesh is erosion of the mesh through the woman's
```

```
Page 107
     vaginal tissues?
 1
 2.
                Restate the question.
           Α.
 3
           O.
                Sure.
 4
                MR. JONES: Can you read it back?
                (Whereupon the Court Reporter read the
 6
                previous question.)
                THE WITNESS: The risk of using any mesh
 7
          is potential erosion.
 8
     BY MR. JONES:
 9
10
                That's a yes, correct?
           Q.
11
           Α.
                That's a yes.
12
           Ο.
                Do you agree that TVT mesh that erodes
13
     through a woman's vaginal tissue can cause pain to a
14
     woman?
15
                I don't attribute that to the mesh, no.
16
           Q.
                Do you agree TVT mesh that erodes through
17
     a woman's vaginal tissue can cause dyspareunia?
18
                I don't attribute that to the mesh.
           Α.
19
           Q.
                Do you believe TVT mesh that erodes
20
     through a woman's vaginal tissue can cause discomfort
     to the woman?
21
22
                That's pretty broad. What do you want to
           Α.
23
     say is discomfort? I mean, how are you describing
     "discomfort"?
24
25
           Q.
                We'll just leave that at that question.
```

```
Page 108
                All right. Is the TVT Retropubic the gold
 1
 2
     standard?
 3
           Α.
                Well --
 4
                MR. MORIARTY: Objection.
                Go ahead.
 6
                THE WITNESS: I have to defer to the AUA,
          AUGS, and SUFU that have described the
 7
          polypropylene mid-urethral sling as the gold
 8
          standard for the treatment --
 9
10
                Now, wait a second. What was your
11
          question?
     BY MR. JONES:
12
13
           Q. Right.
14
                There you go.
                Is TVT Retropubic the gold standard?
15
           O.
16
     or no. To you. I'm asking you.
17
           Α.
                Oh, me?
18
           O.
                Yeah.
                Me. I wouldn't specifically say the
19
           Α.
2.0
     Retropubic.
                In your opinion, is the TVT-Secur the gold
21
           Ο.
22
     standard?
23
                I wouldn't say specifically the Secur.
           Α.
                In your opinion, is the TVT Obturator the
24
     gold standard?
25
```

```
Page 122
                Okay. But if we wanted to know which ones
 1
           Q.
 2
     you looked at, no dice, not going to happen?
 3
                I can't provide you with that.
           Α.
 4
           Q.
                Okay. Do you have any background in
 5
     polymer chemistry?
 6
           Α.
                Again, I don't have a Ph.D., no.
                Have you ever done bench research on
 7
           Ο.
     polypropylene mesh?
8
                Bench research?
 9
           Α.
                                  No.
10
                Lab research on polypropylene mesh?
           Ο.
11
           Α.
                Lab research?
                                No.
12
                Your opinion that TVT mesh does not
           Ο.
13
     degrade in vivo, have you ever attempted to have that
14
     opinion published in a peer review journal?
15
           Α.
                No.
16
           Ο.
                Any of the opinions that you'll be
17
     offering in this litigation, have you ever attempted
18
     to have published in a peer review journal?
19
           Α.
                No.
2.0
                Are the opinions you're offering in this
           Q.
21
     litigation solely for litigation purposes?
22
                MR. MORIARTY: Objection.
23
24
     BY MR. JONES:
25
                I'll withdraw it.
           Q.
```

```
Page 123
                Are you an expert on warnings?
 1
 2
                I'm sorry?
           Α.
 3
           O.
                I'll withdraw that last question. Are you
 4
     an expert on warnings?
           Α.
                Warnings?
 5
                Warnings related to TVT mesh.
 6
           Ο.
                Warnings related to TVT mesh. I'm trying
 7
           Α.
     to consider what an expert in warnings would be.
 8
     Again, I don't know what an expert in warnings would
 9
10
     be.
11
           Ο.
                Have you ever drafted an IFU?
12
           Α.
                No.
                Do you rely in your normal course of
13
           Q.
     practice as a physician on IFUs?
14
           Α.
                Do I rely?
15
16
           Q.
                (Nodding head up and down.)
17
           Α.
                No.
                Do you review IFUs before you use the
18
           Q.
     product?
19
2.0
           Α.
                Yes.
21
                Okay. Always?
           0.
22
           A.
                Which product?
23
                Any product.
           Q.
                It is my usual practice to review IFUs
24
           Α.
     before using a new product.
25
```

```
Page 124
                Thank you. Do you -- are you aware the
 1
           Q.
 2
     industry standards that govern what warnings must be
 3
     in an IFU?
 4
           Α.
                The industry standards? No, I don't know
 5
     that --
                Do you agree that all material risks
 6
     related to the TVT mesh must be included in the IFU?
 7
 8
                MR. MORIARTY: Objection. Form.
                THE WITNESS: I guess define "material
 9
10
          risk."
11
     BY MR. JONES:
12
                It's in your report. How do you use it?
           0.
13
     I'm using your term.
14
                I understand. I just wanted to know on
15
     how you were using it in your question.
                (Off record discussion.)
16
17
           Ο.
                I wish I could let you take all day,
     Doctor, but we're on a tight time frame.
18
                I apologize. I just don't see where I
19
           Α.
2.0
     write on this TVT IFU section the term "material
21
     risk." If you would like to point out to me
22
     specifically where I'm using it, I'll be happy to cut
23
     to the chase for you.
24
           O.
                Yeah. Why don't you go to page 4?
25
     sentence, page 4.
```

```
Page 127
                The risks unique to the proper use of the
 1
     device.
 2
 3
                It's your opinion all risk unique to the
           0.
 4
     TVT device, specifically proper use of the TVT
 5
     device, must be included in the TVT IFU, correct?
 6
                MR. MORIARTY: Objection. Form.
                THE WITNESS: Read it back again. I just
 7
 8
          want to make sure.
                MR. JONES: I'm going fast because I'm on
 9
10
          a tight --
11
                THE WITNESS: I'm with you. I'm sorry. I
12
          apologize. I want to make sure it's right.
13
                MR. JONES: Can you read that question
          back?
14
15
                (Whereupon the Court Reporter read the
16
                requested question.)
17
                THE WITNESS: All risks unique to the TVT
          device.
18
                Yeah, I think that's -- if that's what I
19
2.0
          said, yeah, that's what I mean.
21
     BY MR. JONES:
22
                It's your opinion that, the risks
     associated with the device is caused by improper use
23
     of the device, that risk does not need to be in the
24
25
     IFU, correct?
```

```
Page 128
 1
           Α.
                Correct.
 2
                Okay. What risks are unique to the TVT
           Ο.
 3
     device that need to be in the TVT IFU?
 4
                MR. MORIARTY: Objection. Form.
 5
                Go ahead.
 6
                THE WITNESS: The unique risks to the TVT
          device is erosion of the mesh material.
 7
     BY MR. JONES:
 8
 9
                Is erosion of the mesh material the only
10
     unique device -- or unique risk associated with the
    TVT device?
11
12
                In my opinion, yes.
           Α.
13
                If erosion is the only risk listed in the
           Ο.
14
     TVT IFU, is the TVT IFU adequate, in your opinion?
15
                MR. MORIARTY: Objection. Form.
16
                THE WITNESS:
                              I know you're on a time
17
          constraint, but I'd like to look specifically at
18
          the TVT IFU that you're speaking about.
                MR. MORIARTY: He just asked a
19
20
          hypothetical.
21
                THE WITNESS: I'm sorry? What --
22
                MR. JONES: I think that was an objection.
23
          I'm not for sure, though.
                MR. MORIARTY: I did object.
24
25
                MR. JONES: That was an objection?
```

```
Page 129
                MR. MORIARTY: No. I objected before I
 1
 2
          got out of my seat.
 3
                MR. JONES: Okay. I was talking about
 4
          what you said just then.
    BY MR. JONES:
 5
 6
           Ο.
               I'll ask the question again.
 7
          A. Go ahead.
 8
          Q. Okay.
          A.
               Go ahead.
 9
10
               MR. MORIARTY: No, wait.
11
               MR. JONES: Let me ask my question. Is
12
          that okay?
13
                MR. MORIARTY: Yeah.
14
    BY MR. JONES:
               Is erosion the only unique risk associated
15
           0.
    with the TVT device? Yes or no?
16
17
                MR. MORIARTY: Objection. Form.
18
                Go ahead.
                And asked and answered.
19
2.0
                THE WITNESS: Yes.
21
    BY MR. JONES:
22
           O.
               Okay. If the TVT IFU device only includes
23
     erosion as the unique risk associated with TVT --
               You got a lot detail there. If the TVT
24
          Α.
25
     IFU --
```

Page 130 Q. -- only includes erosion as a risk of the 1 2 device, is the IFU adequate? 3 -- only includes erosion of the TVT 4 device. I mean, in a sense, yeah. In the cadaver labs in educational courses 5 that you've done for Ethicon, have you ever taught 6 anything that is contradicted by the product IFU? 7 Not that I'm aware of. 8 Α. So it's fair to say the information you 9 give to surgeons in these educational labs and 10 seminars are consistent with the content in the 11 instructions for use for that device? 12 13 Α. Yes. 14 Have you ever appeared in any marketing videos for Ethicon? 15 16 I don't recall. I don't recall being 17 asked either. 18 Okay. You have no recollection of Ethicon 0. 19 getting your approval for your use of -- of your 20 likeness in their marketing videos? 21 No, not that I'm aware. Α. 22 O. Okay. Describe to the jury what a normal 23 week in the life of Dr. Carbone is. Define "normal." 24 Α. 25 Q. Limiting it to -- here's what I'm looking

```
Page 131
     for.
 1
 2
           Α.
                Okay.
                       Thanks.
 3
                What you do when you go in as a doctor
           Ο.
 4
     Monday through Friday, or Monday through Sunday.
 5
                I kind of feel like you told me I was
     under a time constraint.
 6
 7
           Ο.
                How about this? What percentage of your
     practice is related to evaluating patients with
 8
 9
     stress urinary incontinence?
10
                25 to 30 percent.
           Α.
11
                What percentage of your practice as an
           Q.
12
     urologist involves treating males?
13
           Α.
                30 percent.
14
                Okay. What percentage of your practice
           Ο.
15
     involves operating on patients with stress urinary
     incontinence?
16
                I guess you'd -- I'd have to ask you, is
17
     this before all the litigation or since all the
18
     litigation?
19
2.0
           Ο.
                Today.
21
           Α.
                Today.
22
                Today, how about -- let me ask the
           Q.
                Today, what percentage of your practice
23
     question.
24
     involves operating on patients related to stress
     urinary incontinence?
25
```

Page 132 20 to 25 percent. 1 Α. 2 Before 2011, what percentage of your 0. 3 practice was related to operating on patients for 4 stress urinary incontinence? Maybe 30, 35 percent. 5 6 Over the past three years, your usage of Q. transvaginal mesh has decreased, correct? 7 Α. 8 Yes. Over the past three years, your usage of 9 TVT mesh has decreased, correct? 10 11 Α. Yes. 12 0. You no longer use transvaginal mesh to 13 treat pelvic organ prolapse whatsoever, correct? 14 Α. Correct. 15 Have you ever used any mesh products Q. 16 transvaginally since the year 2000 that are not made 17 by Ethicon? 18 Α. No. Do you treat mesh complications? 19 Ο. 2.0 Α. Yes. 21 What percentage of your practice is 0. 22 related to mesh -- treating mesh complications? 23 A very small amount. Less than 5 percent. Α. 24 How many -- have you removed mesh from a 25 patient before?

```
Page 133
 1
           Α.
                Yes.
 2
                How many times?
           Ο.
 3
           Α.
                I can't give you an exact count. Slings?
 4
     I'm sorry?
                I was telling him to cut me off on time
 5
           0.
 6
     whenever.
                I apologize. I thought you were talking
 7
           Α.
     about the question.
 8
 9
           Q.
                Sorry.
10
                40 or 50, I guess, in -- now, what -- let
11
     me ask you. What is the time frame you're asking?
12
                Your entire career.
           Ο.
13
           Α.
                What did I say?
14
           O.
                40 or 50.
15
           Α.
                40 or 50. Yeah, that's right.
                                                 That's
16
     about right.
17
                Of those 40 to 50 mesh products you have
           0.
     removed from women, how many are Ethicon mesh
18
19
     products?
2.0
           Α.
                Most of them. I can't give you a number.
21
                In your role as a consultant for Ethicon,
           0.
22
     have you trained sales representatives for Ethicon?
23
           Α.
                Yes.
24
                Have you participated in what's called the
25
     Gynecare sales school?
```

Page 134 I think that's what I was referring to, 1 Α. 2 yes. 3 O. Okay. How long did you participate in the 4 Gynecare sales school? I don't remember how many -- I don't 5 6 remember, but I did participate. Explain to the jury what your role in the 7 Ο. Gynecare sales school was. 8 9 What I did at the Gynecare sales school 10 was to discuss the condition that was appropriate --11 I'm sorry -- the conditions that the product was intended to be used for. 12 13 Did you see your role in the Gynecare 14 sales school as assisting in the education of Ethicon 15 sales reps? 16 Α. Assist. What do you mean by "assist"? 17 Like taught them about the pathophysiology of the 18 disease, rare -- I mean, that's what I taught them 19 about. 2.0 And when you taught Ethicon sales reps in 21 the Gynecare sales school, did you do your best to 22 deliver accurate information to Ethicon sales 23 representatives? 24 Α. On the disease process, yes. 25 Q. Did you ever describe the obturator space

1	CERTIFICATE
2	
3	I, Karen K. Kidwell, RMR, CRR, in and for
4	the Commonwealth of Virginia, do hereby certify that
5	there came before me on Wednesday, March 16, 2016, the
6	person hereinbefore named, who was by me duly sworn to
7	testify to the truth and nothing but the truth of his
8	knowledge concerning the matters in controversy in this
9	cause; that the witness was thereupon examined under
10	oath, the examination reduced to typewriting under my
11	direction, and the deposition is a true record of the
12	testimony given by the witness.
13	I further certify that I am neither attorney
14	or counsel for, nor related to or employed by, any
15	attorney or counsel employed by the parties hereto or
16	financially interested in the action.
17	This the 18th day of March, 2016.
18	
19	$\mathcal{A}(\mathcal{A}, \mathcal{A}) = \mathcal{A}(\mathcal{A})$
20	Karen K. Kidwell, RMR, CRR
21	Notary Public #7625774
22	My Commission Expires: 9/30/2019
23	
24	